

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number	:	10/734,161	Confirmation No.:	2165
Applicant	:	Kevin T. FOLEY		
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Title	:	METHODS FOR PERCUTANEOUS SURGERY		
TC/Art Unit	:	3738		
Examiner:	:	David H. WILLSE		
Docket No.	:	64118.000045		
Customer No.	:	21967		

Commissioner for Patents
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SUGGESTION OF INTERFERENCE
UNDER 37 C.F.R. § 41.202

A. INTRODUCTION

Applicants respectfully suggest, pursuant to 37 C.F.R. § 41.202, that the U.S. Patent and Trademark Office (“USPTO”) declare an interference between the above-identified U.S. Application No. 10/734,161 (“the present application”), assigned to SDGI Holdings, Inc., and U.S. Patent Nos. 6,530,926 and 7,056,321, assigned to Endius Incorporated (hereinafter “the Endius patents”).

B. SUGGESTION OF INTERFERENCE

The information required by § 41.202(a) is set forth below under headings that correspond to the subsections of 37 C.F.R. § 41.202(a).

(1) Identification of the Patents

The patents that include subject matter that interferes with the subject matter claimed in the present application are:

- (a) U.S. Patent No. 6,530,926 (“the ’926 patent”) issued on March 11, 2003 from U.S. Application No. 09/630,077 to Thomas W. Davison for a “Method of Securing Vertebrae”; and

(b) U.S. Patent No. 7,056,321 ("the '321 patent") issued on June 6, 2006 from U.S. Application No. 10/280,489 to James Pagliuca et al. for a "Method of Securing Vertebrae."

The '321 patent is a continuation-in-part of the '926 patent.

(2) Identification of Interfering Claims; Presentation of Proposed Counts; Showing of Correspondence Between Interfering Claims and Proposed Counts

(a) Identification of Interfering Claims

An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa. 37 C.F.R. § 41.203(a).

(i) Proposed Count 1

Applicants respectfully submit that claims 1-6 of the present application interfere with claims 1-12 and 16-17 of the '926 patent and with claims 1-9, 14-22, 26-31 and 34-51 of the '321 patent.

(ii) Proposed Count 2

Applicants respectfully submit that claims 7-8 of the present application interfere with claims 13-15 of the '926 patent and with claims 23-25, 32-33, and 52-64 of the '321 patent.

(b) Presentation of Proposed Counts

Two proposed counts are set forth in Appendix A. The proposed counts are directed to methods for fixing vertebrae of a patient together. Proposed count 1 includes the steps of inserting a cannula into the patient, inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra, inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra, and inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements. Proposed count 2 includes all the steps of proposed count 1 and the additional step of expanding the cannula.

(c) Showing of Correspondence Between the Interfering Claims and the Proposed Counts

A claim corresponds to a count if the subject matter of the count, treated as prior art to the claim, would have anticipated or rendered obvious the subject matter of the claim. 37 C.F.R. § 41.207(b)(2).

(i) Proposed Count 1

Present Application

Claims 1-6 and 9 of the present application correspond to proposed count 1.

Independent claim 1 of the present application corresponds exactly to proposed count 1. Dependent claims 2-4 of the present application merely recite steps that do not define separately patentable subject matter with respect to the subject matter of proposed count 1. For example, claim 2 relates to use of an endoscope, claim 3 recites various conventional steps relating to preparing for and installing a fusion device, and claim 4 recites the step of cutting away tissue at the surgical site using a cutting instrument. Because these steps do not patentably distinguish claims 2-4 from proposed count 1, claims 2-4 should be designated as corresponding to proposed count 1.

Independent claim 5 of the present application is the same as proposed count 1, except that it recites the additional steps of moving a fusion device through the cannula and inserting the fusion device between first and second vertebra of a patient. The use of fusion materials in connection with fixation elements was known in the art prior to Applicants' effective filing date. Accordingly, these additional steps in claim 5, given the subject matter of proposed count 1, do not define separately patentable subject matter with respect to proposed count 1. Claim 5 of the present application should therefore be designated as corresponding to proposed count 1.

Dependent claim 6 of the present application merely recites the additional steps of inserting a tissue retractor into the cannula and shielding tissue at the surgical site. The use of a tissue retractor through a cannula was known in the relevant art prior to Applicants' effective filing date. Accordingly, these additional steps, given the subject matter of proposed count 1, do not define separately patentable subject matter with respect to proposed count 1. Claim 6 of the present application should therefore be designated as corresponding to proposed count 1.

Claim 9 is substantially the same as proposed count 1 except that (a) proposed count 1 recites inserting first, second and third fixation elements through the cannula; whereas claim 9 recites "moving a plurality of fixation elements through the cannula," (b) proposed count 1

recites securing the first and second fixation elements to first and second vertebra and securing the third fixation element to the first and second fixation elements; whereas claim 9 recites “installing the plurality of fixation elements at the surgical site to fix a first vertebra with respect to a second vertebra,” and (c) claim 9 recites that the fixation elements include bone screws. These differences in claim language, however, do not render claim 9 patentably distinct from proposed count 1. Each of the aforementioned recitations in claim 9 would have been obvious in view of proposed count 1. Therefore, claim 9 would have been obvious in view of proposed count 1 and should be designated as corresponding to proposed count 1.

'926 Patent

Claims 1-12 and 16-17 of the '926 patent correspond to proposed count 1. Claim 1 of the '926 patent recites a method of fixing vertebrae of a patient together at a surgical site. Claim 1 of the '926 patent is essentially the same as proposed count 1, except that proposed count 1 recites first, second and third fixation elements (e.g., 2 pedicle screws and 1 plate), whereas claim 1 of the '926 patent recites first and second fasteners (e.g., 2 pedicle screws) and a first fixation element (e.g., a plate). This difference in claim terminology used to describe vertebral fixation elements, such as plates and screws, would have been insignificant to a person skilled in the art of vertebral fixation elements. Accordingly, claim 1 of the '926 patent does not define a patentably distinct invention with respect to proposed count 1.¹

Independent claim 8 of the '926 patent is essentially the same as independent claim 1 and proposed count 1, except that independent claim 8 merely repeats the method with a second cannula at a second surgical site. Accordingly, claim 8 of the '926 patent does not define a patentably distinct invention with respect to proposed count 1.

Independent claim 16 is essentially the same as independent claim 1 and proposed count 1, except that independent claim 16 recites the additional step of cutting away tissue at the surgical site using two cutting tubes, a method that was known for use in the relevant art prior to the filing date of the '926 patent. *See, e.g.*, U.S. Patent No. 5,364,395 at Figure 5. As such,

¹ Applicants note that they alternatively could present count 1 in disjunctive form as reciting claim 1 of the '926 patent “or” claim 1 of the present application. The Board of Patent Appeals and Interferences specifically approved of this practice in *Hsing v. Myers*, 2 USPQ2d 1861, 1862 (BPAI 1987). The issue is the same however, as the difference in terminology is merely a semantic one, not reflecting a difference in inventive concept.

claim 16 does not define separately patentable subject matter, and should be designated as corresponding to proposed count 1.

Dependent claims 2-7, 9-12, and 17 of the '926 patent merely further define elements of independent claims 1, 8, or 16, or recite additional elements that were known for use in the relevant art prior to the filing date of the '926 patent. For example, claims 4-6 and 10-11 merely further define the recited fasteners and fixation elements as bone screws, plates, and rods, that were known in the art prior to the filing date of the '926 patent. *See, e.g.*, U.S. Patent No. 5,569,248 at col. 7, line 53 - col. 8, line 9 and Figures 1-3. Claims 3, 7 and 12 each recite conventional steps relating to preparation for and insertion of a fusion device between two vertebrae. Claims 2 and 9 relate to use of an endoscope. Claim 17 relates to use of a blood coagulation device, that was known in the art prior to the filing date of the '926 patent. *See, e.g.*, U.S. Patent No. 5,364,395 at col. 14, lines 4-9 and Figures 16-17. As such, these dependent claims do not define separately patentable subject matter with respect to proposed count 1, and therefore should be designated as corresponding to proposed count 1.

'321 Patent

Claims 1-9, 14-22, 26-31 and 34-51 of the '321 patent correspond to proposed count 1.

Claim 1 of the '321 patent is essentially the same as proposed count 1, except that (a) proposed count 1 recites first, second and third fixation elements (*e.g.*, 2 pedicle screws and 1 plate), whereas claim 1 of the '321 patent recites first and second fasteners (*e.g.*, 2 pedicle screws) and a first fixation element (*e.g.*, a plate); (b) claim 1 of the '321 patent recites the additional steps of moving a fusion device through the cannula and inserting the fusion device between first and second vertebra of a patient; and (c) claim 1 of the '321 patent recites fixing the first fixation element to the first and second fasteners "after at least one of the fasteners has been secured to the first or second vertebra."

However, with respect to (a), as discussed above for claim 1 of the '926 patent, the difference in claim terminology for the vertebral fixation elements, *i.e.*, "fastener" vs. "fixation element," is insignificant. With respect to (b), the use of fusion devices in connection with fixation elements was known in the art prior to the effective filing date of the '321 patent. *See, e.g.*, U.S. Patent No. 5,569,248. With respect to (c), the procedure of securing a first pedicle screw to a first vertebra, securing a second pedicle screw to a second vertebra, and then securing a plate to the first and second pedicle screws was well known in the art. *See, e.g.*, U.S. Patent

No. 5,395,371 at col. 6, lines 28-46 (“Once a pedicle screw means 40 has been threaded into each of the tapped openings in the vertebrae V, the fixation plate 13 can be placed against the arcuate surfaces 47 of each of the pedicle screw means 40. . . .”); U.S. Patent No. 5,196,015 at col. 1, lines 21-27 (“Instrument systems that accomplish spinal fixation are known in the form of pedicle screws which are adapted to be inserted in selected vertebrae, and stiff rods or plates that connect adjacent pedicle screw heads to one another after the screws are inserted, thus resulting in the fixing or bracing of all vertebrae spanned by the rod or plate.”). Accordingly, these additional recitations in claim 1 of the ’321 patent do not define separately patentable subject matter with respect to proposed count 1.

Dependent claims 2-9 and 14-17 of the ’321 patent merely further define elements of claim 1 or recite the addition of elements that were known for use in the relevant art prior to the filing date of the ’321 patent. As such, they do not define separately patentable subject matter, and should be designated as corresponding to proposed count 1 along with claim 1 of the ’321 patent. For example, claims 2, 3, 7, 8, and 9 merely repeat one or more of the steps already recited in claim 1 of the ’321 patent for additional fixation elements. With respect to claims 4-6 and 14, these claims merely recite the addition of elements, *e.g.*, the use of tissue retractors and allograft material, that were known for use in the relevant art prior to the filing date of the ’321 patent or are obvious variations thereof. *See, e.g.*, U.S. Patent No. 5,613,937 at col. 10, lines 30-35 (describing a tissue retractor) and U.S. Patent No. 6,485,518 at col. 6, lines 33-47 (describing allograft material). *See also* ’321 patent at col. 29, lines 30-31 (“The implant 2110 is formed by harvesting allograft material from a femur, as is known in the art.”). Claim 15 recites a limitation that would have been obvious in view of proposed count 1. In particular, given that proposed count 1 recites inserting a cannula into the patient and inserting first, second and third fixation elements through the cannula, it would have been obvious to move the fixation elements through the cannula “without removing the cannula from the patient.” Claims 16-17 recite that the cannula (claim 16) or elongate body (claim 17) is inserted into a back of the patient. The use of a cannula for back surgery was well known in the art prior to the filing date of the ’321 patent. *See, e.g.*, U.S. Patent No. 5,439,464. Accordingly, claims 2-9 and 14-17 do not define separately patentable subject matter with respect to proposed count 1.

Similarly, claims 18-22, 26-31 and 34-51 of the ’321 patent are not patentably distinguishable from proposed count 1. For example, independent claim 18 is essentially the

same as independent claim 1, except that claim 18 recites an “elongate body” whereas claim 1 recites a “cannula” and claim 18 recites a “member” whereas claim 1 recites a “first fixation element.” These differences in terminology are not significant and therefore the analysis set forth above as to why claim 1 corresponds to proposed count 1 applies equally to claim 18. Independent claim 22 is substantially the same as claim 1, with a few minor exceptions. In particular, claim 22 recites features of the elongate body which are well known features of many cannulae (e.g., proximal end, distal end, outer surface, inner surface, etc.); claim 22 uses the term “implant” rather than “fastener”; claim 22 uses the term “coupling” rather than the term “securing”; and claim 22 uses the term “spanning member” rather than “first fixation element.” These differences in terminology are not significant and therefore the analysis set forth above as to why claim 1 corresponds to proposed count 1 applies equally to claim 22. Accordingly, independent claims 18 and 22 of the ’321 patent should be designated as corresponding to proposed count 1.

Dependent claims 19-21, 26-31 and 34-51 of the ’321 patent merely further define elements of claim 18 or claim 22 or recite the addition of elements that were known for use in the relevant art prior to the filing date of the ’321 patent. For example, claim 19 recites a fixation element and claim 20 recites a rigid member configured to substantially prevent movement between the first vertebra and the second vertebra. Both of these features were well known in the art. Claim 21 recites a feature that would have been obvious given the subject matter of proposed count 1. In particular, given that proposed count 1 recites inserting a cannula into the patient and inserting first, second and third fixation elements through the cannula, it would have been obvious to move these elements through an elongate body (the cannula) “without removing the elongate body from the patient.” Claims 26-31 and 34-51 recite known elements and features of vertebral fixation systems or elements or features that would have been obvious in view of proposed count 1. For example, claims 26-31 recite pedicle screws, rods, plates and nuts. Claims 34-51 recite well known features and elements of vertebral fixation systems or elements commonly used with vertebral fixation systems, such as an endoscope, cutting tools, tissue removal, disk removal, bone graft tissue, fusion cages, etc. As such, these dependent claims do not define separately patentable subject matter with respect to proposed count 1 and should be designated as corresponding to proposed count 1.

For the foregoing reasons, Applicants respectfully submit that claims 1-9, 14-22, 26-31 and 34-51 of the '321 patent correspond to proposed count 1.

(ii) Proposed Count 2

Present Application

Claims 7-8 of the present application correspond to proposed count 2. Independent claim 7 of the present application corresponds exactly to proposed count 2. Dependent claim 8 merely recites the step of shifting the cannula in the body to position the cannula at a desired location in the body. This additional step of claim 8, given the subject matter of proposed count 2, does not define separately patentable subject matter with respect to the subject matter of proposed count 2. Accordingly, claims 7-8 of the present application should be designated as corresponding to proposed count 2.

'926 Patent

Claims 13-15 of the '926 patent correspond to proposed count 2. Independent claim 15 of the '926 patent recites a method of fixing vertebrae of a patient together at a surgical site. Claim 15 of the '926 patent is essentially the same as proposed count 2, except that (a) proposed count 2 recites first, second and third fixation elements (*e.g.*, 2 pedicle screws and 1 plate), whereas claim 15 of the '926 patent recites first and second fasteners (*e.g.*, 2 pedicle screws) and a first fixation element (*e.g.*, a plate); and (b) proposed count 2 recites "expanding the cannula," whereas claim 15 recites "expanding the first cannula at its end adjacent the first and second vertebrae." Neither of these differences renders claim 15 patentably distinct from proposed count 2. For example, as discussed above with respect to proposed count 1, the difference in terminology used for vertebral fixation elements, *i.e.*, "fastener" vs. "fixation element," is insignificant. Furthermore, the recitation in proposed count 2 of "expanding the cannula" obviously contemplates a cannula that is expanded "at its end adjacent the first and second vertebrae," as recited in claim 15 of the '926 patent. Accordingly, claim 15 of the '926 patent should be designated as corresponding to proposed count 2.

Dependent claim 13 of the '926 patent is essentially the same as proposed count 2, except for the insignificant differences discussed above relating to (a) the terminology used to describe the fixation elements; (b) repeating the method with a second cannula; and (c) the recitation of

expanding the cannula. Accordingly, dependent claim 13 is patentably indistinguishable from proposed count 2 and therefore should be designated as corresponding to proposed count 2.

Dependent claim 14 merely recites the additional step of “shifting the first and second cannulae in the body to position the first and second cannulae to desired locations in the body.” This additional step of claim 14, given proposed count 2, does not define separately patentable subject matter with respect to the subject matter of proposed count 2. Accordingly, claim 14 of the present application should be designated as corresponding to proposed count 2.

’321 Patent

Claims 23-25, 32-33, and 52-64 of the ’321 patent correspond to proposed count 2.

Claim 23 of the ’321 patent recites a method for providing treatment at or near the spine. Claim 23 of the ’321 patent is essentially the same as proposed count 2, except that (a) proposed count 2 recites a “cannula” whereas claim 23 recites “an elongate body” and various well-known features of a cannula such as a proximal end, a distal end, an outer surface, etc., (b) proposed count 2 recites first, second and third fixation elements (*e.g.*, 2 pedicle screws and 1 plate), whereas claim 23 recites first and second “implants” (*e.g.*, 2 pedicle screws) and a “spanning member” (*e.g.*, a plate); (c) claim 23 of the ’321 patent recites fixing the first fixation element to the first and second fasteners “after at least one of the fasteners has been secured to the first or second vertebra,” and (d) proposed count 2 recites “expanding the cannula,” whereas claim 23 recites “expanding the elongate body after the distal end of the elongate body is proximate the surgical location.” None of these differences renders claim 23 patentably distinct from proposed count 2. For example, with respect to (a), the term “elongate body” and its recited conventional features is patentably indistinguishable from a cannula. With respect to (b), the difference in terminology used for vertebral fixation elements, *i.e.*, “implant” vs. “fixation element,” is insignificant. With respect to (c), the procedure of securing a first pedicle screw to a first vertebra, securing a second pedicle screw to a second vertebra, and then securing a plate to the first and second pedicle screws was well known in the art, as discussed above with respect to claim 1 of the ’321 patent. *See, e.g.*, U.S. Patent Nos. 5,395,371 and 5,196,015. With respect to (d), the recitation in proposed count 2 of “expanding the cannula” obviously contemplates a cannula that is expanded after its distal end is proximate to the surgical location. Accordingly, claim 23 of the ’321 patent should be designated as corresponding to proposed count 2.

Dependent claims 24-25 merely further define elements that would have been obvious given the subject matter of proposed count 2. For example, given that proposed count 2 recites “expanding the cannula” and a cannula generally refers to a tube having a continuous surface, it would have been obvious to have a continuous surface prior to (claim 24) and after (claim 25) the expanding step. Accordingly, claims 24 and 25 do not define separately patentable subject matter and should be designated as corresponding to proposed count 2 along with claim 23 of the ’321 patent.

Claims 32-33 of the ’321 patent are also patentably indistinguishable from proposed count 2. Claim 32 is essentially the same as claim 23, analyzed above, except that claim 32 describes an expanded cannula in alternate terms, *i.e.*, an “elongate body” with a cross sectional area at a first location greater than the cross sectional area at a second location. This difference in terminology is not significant and therefore the reasons set forth above as to why claim 23 corresponds to proposed count 2 apply equally to claim 32. Dependent claim 33 merely adds the explicit recitation of expanding the elongate body after the distal end is proximate to the surgical location, which does not render claim 33 patentably distinguishable from proposed count 2.

Likewise, claims 52-58 and 59-64 also recite subject matter that would have been obvious in view of proposed count 2. Applicants have previously analyzed the various features recited in these claims and have explained why they are not patentably significant. Accordingly, claims 52-58 and 59-64 are obvious in view of proposed count 2 and should be designated as corresponding to proposed count 2.

For the foregoing reasons, Applicants respectfully submit that claims 23-25, 32-33, and 52-64 of the ’321 patent should be designated as corresponding to proposed count 2.

(3) Claim Charts Comparing The Claims' Correspondence to the Proposed Counts and Showing of Why the Claims Interfere

In accordance with 37 C.F.R. § 41.202(a)(3), attached Appendix B sets forth a side-by-side comparison of proposed count 1, independent claim 1 of the present application, independent claim 1 of the ’926 patent, independent claim 1 of the ’321 patent, and a showing of why these claims interfere. Appendix B also sets forth a side-by-side comparison of proposed count 2, independent claim 7 of the present application, independent claim 15 of the ’926 patent, claim 23 of the ’321 patent, and a showing of why these claims interfere.

(4) Explanation of Why Applicants Will Prevail on Priority

Claims 1-6 and 9 of the present application are entitled to the filing date of U.S. Patent No. 5,792,044, filed March 22, 1996. Claims 7-8 of the present application are entitled to the filing date of U.S. Patent No. 5,902,231, filed October 24, 1996. These filing dates are prior to the filing date of August 1, 2000 of the '926 patent and the filing date of October 25, 2002 of the '321 patent. Therefore, Applicants will prevail on priority.

(5) Claim Chart Showing Written Description for Each Claim in Applicants' Specification

Attached as Appendix C is a claim chart which sets forth the written description support in the present application for each of Applicants' interfering claims.

(6) Chart Showing Support for a Constructive Reduction to Practice Within the Scope of the Interfering Subject Matter

Attached as Appendix D are claim charts which set forth exemplary disclosure in each of the priority applications showing constructive reduction to practice within the meaning of 37 C.F.R. § 41.201 of the claims of the present application within the scope of the interfering subject matter corresponding to proposed counts 1 and 2.

C. CONCLUSION

In view of the foregoing, Applicants respectfully request that the U.S. Patent and Trademark Office declare an interference between the present application and the '926 and '321 patents.

If the Examiner believes that prosecution or declaration of the interference might be advanced by discussing the application or the contents of this Suggestion of Interference with Applicants' counsel, in person or by telephone, the undersigned would welcome the opportunity to do so.

It is believed that no fees are due with this Suggestion of Interference. However, in the event any fees are due, the Director is hereby authorized to charge the undersigned's Deposit Account No. 50-0206.

U.S. APPLICATION NO. 10/734,161
SUGGESTION OF INTERFERENCE

Respectfully submitted,

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